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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/551,705	07/14/2006	Michael James Moser	023542-0145	3640

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EXAMINER	
BOWMAN, AMY HUDSON	
ART UNIT	PAPER NUMBER
1635	
MAIL DATE	DELIVERY MODE
01/26/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/551,705	MOSER ET AL.	
	Examiner	Art Unit	
	AMY BOWMAN	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 April 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-27* is/are pending in the application.

4a) Of the above claim(s) *10,14 and 18-25* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9, 11-13, 15-17, 26, and 27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *30 September 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *7/14/06, 8/17/06, 3/24/09, 10/23/09*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's election without traverse of group I, claims 1-17, 26, and 27, and the species of two separate nucleic acids and DNA or DNA mimetic, in the reply filed on 4/17/09 is acknowledged.

Claims 10, 14, and 18-25 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 4/17/09.

Information Disclosure Statement

The information disclosure statements (IDS) submitted on 7/14/06, 8/17/06, 3/24/09, and 10/23/09 have been considered by the examiner.

Claim Objections

Claim 15 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 15 requires for the nucleic acid portion of the polymerase inhibitor to be resistant to nuclease degradation, but does not set forth any structural requirement to further limit claim 1.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-6, 11, 13, 15-17, 26, and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by Kainz (BioTechniques, 2000, 28(2), pages 278-282) (of record and cited on the IDS filed on 3/24/09).

The instant claims are directed to a polymerase inhibitor with the structural characteristics set forth in the instant claims.

Kainz teaches double stranded DNA fragments which, without acting as a template for extension, inhibit the activity of DNA polymerases. Kainz teach that this inhibition occurs independently of the sequence of the fragment and depends only upon the melting temperature of the fragment (see page 278). Kainz teaches that the fragments were tested against a variety of DNA polymerases to determine their ability to inhibit DNA polymerase enzymes from unrelated families, including Taq DNA polymerase, Vent DNA polymerase, and Pwo DNA polymerase (see page 278, Materials and Methods: DNA polymerases). The DNA fragments are between 17-20 basepairs in length, with melting temperatures in the range of 40 C to 60 C (see page 279, table 1).

Although Kainz does not specifically utilize kit language, Kainz teaches each of the components required by the instant kit to be used in combination.

Claim 15 requires for the nucleic acid portion of the polymerase inhibitor to be resistant to exonuclease degradation but does not set forth any structural difference other than the requirements of claim 1 and therefore the nucleic acids of Kainz necessarily meet this limitation via meeting the limitations of claim 1.

Therefore, the instant claims are anticipated by Kainz.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation

under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-9, 11-13, 15-17, 26, and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kainz (BioTechniques, 2000, 28(2), pages 278-282), in view of Newton et al. (Nucleic Acids Research, 1993, Vol. 21, No. 5, pages 1155-1162).

The instant claims are directed to a polymerase inhibitor with the structural characteristics set forth in the instant claims.

Kainz teaches double stranded DNA fragments which, without acting as a template for extension, inhibit the activity of DNA polymerases. Kainz teach that this inhibition occurs independently of the sequence of the fragment and depends only upon the melting temperature of the fragment (see page 278). Kainz teaches that the fragments were tested against a variety of DNA polymerases to determine their ability to inhibit DNA polymerase enzymes from unrelated families, including *Taq* DNA polymerase, *Vent* DNA polymerase, and *Pwo* DNA polymerase (see page 278, Materials and Methods: DNA polymerases). The DNA fragments are between 17-20 basepairs in length, with melting temperatures in the range of 40°C to 60°C (see page 279, table 1).

Although Kainz does not specifically utilize kit language, Kainz teaches each of the components required by the instant kit to be used in combination. It would have

been obvious to formulate the components in a kit, given that each of the components was known to be used in combination to inhibit polymerase activity.

Claim 15 requires for the nucleic acid portion of the polymerase inhibitor to be resistant to exonuclease degradation but does not set forth any structural difference other than the requirements of claim 1 and therefore the nucleic acids of Kainz necessarily meet this limitation via meeting the limitations of claim 1.

Kainz does not teach incorporation of single stranded 3' or 5' ends; or caps.

Incorporation of single stranded 3' or 5' ends into the dsDNA fragments of Kainz, as well as incorporation of a blocking moiety, is considered within the realm of routine optimization, given these is elements routine to the skilled artisan and aimed at achieving the same results as the fragments of Kainz.

Given that the polymerase of Kainz is a ds polymerase, it would have been obvious to incorporate a single-stranded portion at the 3' or 5' end that is not complementary to the target sequence, or to incorporate a block, as each of these are routine means of terminating polymerase extension, which is the same purpose as the terminating polymerase activity as the short dsDNA segments themselves. Therefore, one would expect for these elements to achieve inhibition of polymerase activity.

Thus in the absence of evidence to the contrary, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to AMY BOWMAN whose telephone number is (571)272-0755. The examiner can normally be reached on Monday-Thursday 6:00 - 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tracy Vivlemore can be reached on (571) 272-2914. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

AMY BOWMAN
Primary Examiner
Art Unit 1635

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